

Exhibit 20

*State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Laboratories, Inc., et al.*

Exhibit to the Declaration of Rita Hanscom in Support of
Plaintiffs' Opposition to Dey, Inc. and Dey, L.P.'s Motion for Partial Summary Judgment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
**OFFICE OF
INSPECTOR GENERAL**

**Medicaid's Use of Revised
Average Wholesale Prices**



JANET REHNQUIST
INSPECTOR GENERAL

SEPTEMBER 2001
OEI-03-01-00010

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

This report describes State Medicaid agencies' use of revised average wholesale prices for certain prescription drugs.

BACKGROUND

Medicaid payments for prescription drugs totaled almost \$12 billion in 1998, accounting for nearly 7 percent of all Medicaid expenditures. Most State Medicaid agencies reimburse pharmacies based on the average wholesale price of a drug less a discount ranging from 4 to 15 percent. States do not always use the same reimbursement for drugs administered directly by physicians. Drug manufacturers report average wholesale prices to companies such as First DataBank and Medical Economics. These companies compile pricing data for the pharmaceutical industry.

Recently, a national investigation conducted by the United States Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU) revealed that some drug manufacturers were reporting inflated average wholesale prices for certain products. As a result, the two entities collected actual wholesale pricing data for approximately 400 national drug codes representing 51 drugs. This data was provided to First DataBank, who calculated new average wholesale prices for the drugs, and subsequently made the revised prices available to State Medicaid programs. The NAMFCU strongly encouraged States to make use of the revised prices, and anticipated that their implementation would result in a significant reduction in Medicaid reimbursement for the drugs involved.

We gathered information from Medicaid representatives in 48 States and the District of Columbia. We asked States about their drug reimbursement methodologies, whether or not they had implemented the revised average wholesale prices, and if they had any problems or concerns about these prices. We also asked States that had implemented the revised prices to provide cost-savings estimates, if available.

FINDINGS

Thirty States use at least some of the revised average wholesale prices when determining drug reimbursement amounts

Thirty States have incorporated the revised prices into their drug reimbursement methodology in some manner. However, States vary considerably in their methods of

implementation. Of the 30 States that have adopted the revised prices, 9 States use them for both pharmacy drugs and physician-administered drugs. The remaining 21 States use the revised prices for pharmacy drugs only.

States reported both advantages and disadvantages to using the revised prices

Seven States expressed complete support of the efforts to revise drug prices. These States noted that reported average wholesale prices are often extremely inflated, and they welcomed the efforts to obtain more accurate prices. Seventeen States appreciated the intent of the revised prices, but questioned whether the effort was the best solution. Nearly all States reported that certain groups opposed the use of the revised average wholesale prices. Opposition came from a number of sources, including hemophilia groups, pharmacies, infusion providers, physicians, and drug manufacturers.

States using the revised prices believe they will lead to short-term cost-savings, but are unsure of the long-term impact

Of the 30 States who are currently using the revised prices, 24 believed the prices will result in short-term cost-savings. However, 20 of the 30 States either do not believe or are unsure that the new prices will lead to any long-term savings. Seven States provided cost-savings estimates, with annual savings ranging from \$800,000 to \$7 million.

CONCLUSION

Over the last several years, the OIG has produced a significant body of work that clearly demonstrates the inflated nature of reported average wholesale prices. Because most States base their reimbursement for drugs on average wholesale prices, this inflation has caused Medicaid to pay too much for certain products. Therefore, we commend any efforts to obtain more accurate pricing for the Medicaid program.

This report shows that some States are benefitting from the revised average wholesale prices prompted by the actions of the Justice Department and the NAMFCU. However, States' concerns about the revised prices indicate that attempting to lower reimbursement simply by further reducing average wholesale prices may not be an effective long-term solution. Therefore, we continue to believe that the current system's reliance on reported average wholesale prices as a basis for drug reimbursement is fundamentally flawed.

Agency Comments

The CMS agreed with our conclusion that the reliance on reported average wholesale prices as a basis for drug reimbursement is problematic, and stated that they will continue to look for administrative and legislative solutions to this problem. In addition, the CMS made two technical comments concerning items in the draft report. We have addressed the technical comments in this final version of the report.

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INTRODUCTION

PURPOSE

This report describes State Medicaid agencies' use of revised average wholesale prices for certain prescription drugs.

BACKGROUND

Congress created Medicaid in 1965 under Title XIX of the Social Security Act. Medicaid is a joint Federal and State program that provides medical assistance to individuals and families with low incomes and few resources. Individual States establish eligibility requirements, benefits packages, and payment rates for Medicaid under broad standards set by the Centers for Medicare & Medicaid Services (CMS). The Federal Government contributes between 50 and 83 percent of the Medicaid funding for each State. In 1998, Medicaid helped provide approximately 40 million people with medical assistance, at a cost of over \$175 billion.

Medicaid Coverage of Prescription Drugs

Federal guidelines require States to provide certain benefits, such as hospital and physician services, to their Medicaid recipients. Each State also has the option of providing other Medicaid benefits, including prescription drugs. Currently, all 50 States and the District of Columbia offer prescription drug coverage for Medicaid recipients. Medicaid payments for prescription drugs totaled almost \$12 billion in 1998, accounting for nearly 7 percent of all Medicaid expenditures.

Most outpatient prescription drugs are covered by Medicaid. However, States often have different reimbursement methods for drugs obtained through pharmacies versus drugs administered in physicians' offices. Drugs purchased from pharmacies are covered and reimbursed under States' prescription drug programs. In contrast, drugs administered by physicians are usually reimbursed through the physician payment process, and not the prescription drug program.

Pharmacies use national drug codes to identify and obtain reimbursement for drugs covered under a State's prescription drug program. Each drug manufactured or distributed in the United States has a unique national drug code that identifies the manufacturer of the drug, the product dosage form, and the package size. Physicians, however, often bill Medicaid for drugs on the HCFA 1500 claim form, which does not specifically request national drug code information. On the HCFA 1500 form, drugs are identified by codes in the HCFA Common Procedure Coding System, hereinafter referred

to as procedure codes. Procedure codes define the type of drug and the dosage amount, but not the specific drug product or its manufacturer.

Medicaid Drug Reimbursement Methodology

Each Medicaid agency is required to submit a State plan to CMS describing its payment methodology for covered drugs. Federal regulations require that each State's reimbursement for a drug not exceed, in the aggregate, the lower of its estimated acquisition cost or the providers' usual and customary charge to the public for the drug. However, CMS allows States flexibility in defining estimated acquisition cost.

When reimbursing for a pharmacy drug, 43 State Medicaid agencies base their calculation of estimated acquisition cost on the drug's average wholesale price discounted by 4 to 17 percent. Four other States use wholesale acquisition cost plus 5 to 11 percent when calculating estimated acquisition cost. Three States use a combination of both methods. Drug manufacturers report average wholesale prices to companies such as First DataBank and Medical Economics. These companies compile pricing data for the pharmaceutical industry. This pricing data is usually reported using national drug codes rather than procedure codes.

For certain pharmacy drugs, States use the Federal Upper Limit and the State Maximum Allowable Cost programs in determining reimbursement amounts. The CMS has established Federal upper limit payment amounts for over 200 drugs. In addition, more than half of States have implemented a maximum allowable cost program to limit payment amounts for certain prescription drugs. States vary considerably in the method by which this maximum allowable cost is calculated. A small number of States use other pricing mechanisms for specific categories of drugs, such as blood factors used in the treatment of hemophilia. These States may obtain prices directly from manufacturers, require invoices from providers that show actual acquisition costs, or calculate reimbursement through various other methods.

Many States reimburse physician-administered drugs differently than pharmacy drugs. The majority of States still base reimbursement for physician-administered drugs on average wholesale price. However, some States discount average wholesale prices by different amounts for physician drugs compared to pharmacy drugs, while other States subtract no discount at all. Many physician-administered drugs are billed using procedure codes that do not have corresponding average wholesale prices. Therefore, calculating reimbursement amounts for physician-administered drugs can be more complicated than for pharmacy drugs.

Overall, most Medicaid States reimburse for drugs purchased from a pharmacy at the lower of the discounted average wholesale price, the Federal upper limit, the State maximum allowable cost, or the provider's usual and customary charge. States often reimburse for physician-administered drugs in a different manner, though most still use average wholesale price as the primary basis for determining reimbursement.

Revised Drug Prices for Medicaid

A recent investigation conducted by the United States Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU) revealed that some drug manufacturers were reporting inflated average wholesale prices for certain products. The investigation suggested that these inflated prices have caused the Medicaid program to overpay substantially for these drugs. As a result, the Justice Department and the NAMFCU collected actual average wholesale pricing data for approximately 400 of the more than 50,000 national drug codes presently in use. These 400 codes represent 51 injectable, infusion, and inhalation drugs. The data was gathered from several wholesale drug catalogs.

In a February 2000 letter to State Medicaid pharmacy directors, the NAMFCU stated that the pricing data had been given to First DataBank, the company that provides average pricing information to nearly all of the State Medicaid agencies. First DataBank agreed to use this data to calculate revised average wholesale prices for the 51 drugs, and to subsequently make the revised prices available to the States. In encouraging the States to take advantage of these revised prices, the NAMFCU wrote:

This revised procedure does not change the terms of the company's [First DataBank's] contract with your State, but merely provides an improved means for First DataBank to provide more accurate information to the States. More importantly, in view of the Medicaid program's legal obligation to reimburse true provider acquisition costs, such an effort by the States to ensure that payment is based on actual prices is mandatory.

According to the letter, Medicaid agencies may make changes to the list of national drug codes with revised prices. First DataBank agreed that every six months it would collect information from wholesale catalogs when updating prices for the approximately 400 national drug codes. The NAMFCU anticipated that the use of the revised prices would result in a significant reduction in reimbursement for the drugs involved.

First DataBank began reporting the revised average wholesale prices to States on May 1, 2000. However, some States did not wish to use the revised prices, and requested that First DataBank continue to supply the original prices instead.

METHODOLOGY

We reviewed relevant information about the Medicaid program, specifically materials relating to Medicaid drug reimbursement. In addition, we obtained correspondence from First DataBank and the NAMFCU concerning the implementation of the revised average wholesale prices.

Data Collection and Analysis

We conducted telephone interviews with Medicaid representatives in 48 States and the District of Columbia, hereinafter referred to as a State. Whenever possible, the interview was conducted with the States' drug program administrator. We did not speak with Medicaid staff from Arizona because the State's drug benefit is administered completely through managed care organizations and not the traditional fee-for-service system. Representatives of Maine's Medicaid program did not respond to our request for an interview. In this report, we use the word "State" to denote both a "State Medicaid agency" and "State Medicaid agency representative."

Before contacting the States, we developed questions about the revised average wholesale prices with the assistance of CMS staff and two State drug program administrators. We asked States about their drug reimbursement methodologies, whether or not they had implemented the revised average wholesale prices, and if they had any problems or concerns about these prices. We also asked States that had implemented the revised prices to provide cost-savings estimates. However, we did not validate the cost-savings estimates reported by States. We also gave each State an opportunity to discuss any other issues they felt needed to be addressed concerning the revised average wholesale prices. We collected this data between January and March 2001.

FINDINGS

Thirty States use at least some of the revised average wholesale prices when determining drug reimbursement amounts

Thirty States have incorporated the revised prices into their drug reimbursement methodology in some manner. However, States vary considerably in the methods of implementation. For the most part, States use these prices as one of the factors in calculating a drug's reimbursement amount. States continue to use Federal upper limits, State maximum allowable costs, and various other pricing methods in combination with the revised average wholesale prices calculated by First DataBank.

Because the revised average wholesale prices are based on national drug codes, many States have found it difficult to use them for physician-administered drugs, which are usually reimbursed by procedure code. Of the 30 States that have adopted the revised prices, nine States use them for both pharmacy drugs and physician-administered drugs. The remaining 21 States use the revised prices for pharmacy drugs only. A table outlining how each State uses the revised prices is provided in appendix A.

Some States do not use the revised prices for certain drug products. For example, two States discontinued using the revised prices for blood factors. Three other States that base reimbursement primarily on wholesale acquisition cost or direct pricing use the revised prices only when these other prices are not available. One State cannot use the revised average wholesale prices for certain claims because First DataBank refused to provide the revised prices to one of the State's contractors.

Eleven States do not take a percentage discount off the revised average wholesale prices

When determining reimbursement, States generally subtract a percentage discount from the drug's average wholesale price. However, 11 of the 30 States that use the revised prices do not subtract this percentage discount when paying for drugs that have revised prices. Several States reported that the revised average wholesale prices are closer to a true acquisition cost; therefore, subtracting a percentage discount may actually make the reimbursement amount fall below a provider's acquisition cost. They remarked that if providers were reimbursed below cost, they would simply stop providing these drugs, which could limit a patient's access to care.

Several other States have considered eliminating the percentage discount when determining reimbursement for the drugs with revised prices. However, these States are

unsure they have the authority to change their reimbursement methodology for this small group of drugs without undertaking significant administrative and/or legislative actions.

States reported both advantages and disadvantages to using the revised prices

Some States were completely supportive of the efforts to revise prices

Seven States reported only positive opinions about the revised prices. These States noted that reported average wholesale prices are often extremely inflated, and they welcomed the Justice Department's and NAMFCU's efforts to obtain more accurate prices. One State pharmacy director said, "This kind of pricing information should be aggressively pursued by First DataBank, the OIG, and HCFA." Two other pharmacy directors hoped that the revised pricing would be expanded to even more drugs.

Other States appreciated the intent of the revised prices, but questioned whether the effort was the best solution

Seventeen States supported the efforts to revise prices, but had concerns with the specific actions taken. Four of these States believed that attempts to reduce excessive reimbursement for prescription drugs should not be based on determining more accurate average wholesale prices. According to these States, basing payment on the actual acquisition cost of a drug or on the average manufacturer's price reported to CMS under the Medicaid Drug Rebate Program is a much more effective solution. The other 13 States did not report problems with the use of average wholesale prices in general. Rather, they cited concerns about the particular drugs included in the revisions and questioned how the revised prices would be updated.

Several States noted that the drugs chosen for pricing revisions were mainly infusion and injectable products that did not amount to a significant portion of Medicaid drug spending. One respondent termed these drugs "small potatoes," and felt that price reductions should have been targeted to a different class of products such as oral tablets. Others noted that basing the revisions on specific national drug codes rather than entire drug classes could potentially limit the effectiveness of the revisions.

States also expressed concern about the process of updating the revised prices. Even though First DataBank is required by its agreement with the NAMFCU to collect updated prices for these drugs, some States reported that First DataBank expressed little interest in updating the revised prices. According to these States, First DataBank only planned on reporting revised prices based on what the Justice Department and the NAMFCU provided them. Meanwhile, States were unsure if the Justice Department and the NAMFCU were planning to provide updated pricing information to First DataBank and/or add any new national drug codes to the pricing revisions.

Some States felt these problems were never addressed because the Justice Department and the NAMFCU sought little or no input from State drug program administrators. According to one State, many of the concerns States have with the revised prices could have been avoided if the drug program administrators had been included in the decision-making process.

States reported that certain groups opposed the use of the revised average wholesale prices

Forty-three States reported receiving complaints about the revised prices. These complaints were from a number of sources, including hemophilia groups, pharmacies, infusion providers, physicians, and drug manufacturers. All asserted that the revised prices were too low. Some hemophilia providers claimed that they would be unable to continue treating Medicaid recipients unless the prices for blood factors were raised. These complaints were instrumental in two States' decisions to discontinue the use of the revised prices for blood-factor products, and have caused other States to contemplate the same action. In addition, some States volunteered that they had asked drug providers for invoices to substantiate claims that the revised prices were below acquisition costs. These States reported that invoice data was either not provided, or provided only for a very small number of drug codes (less than 10). In these cases, the States made revisions to prices based on the invoice data.

The majority of the 19 States that are not using the revised prices felt that the prices may be too low, especially when a percentage discount is subtracted. Four of these 19 States actually used the revised prices at one time, but later reversed their decisions. Some States noted they checked with area wholesalers and distributors, and subsequently determined that the revised prices were not readily available to providers in their State.

States using the revised prices believe they will lead to short-term savings, but are unsure of the long-term impact

Of the 30 States currently using the revised prices, 24 believed there will be short-term cost savings. These States reported that short-term savings were inevitable due to significant per-unit price reductions for these drugs. However, some States suggested the savings would be small because there was low utilization for the drugs with revised prices, or that utilization for these drugs would simply shift to other products.

Seven States provided an estimate of annual cost savings that would result from their drug price revisions. Each of these estimates was based on the assumption that utilization would remain constant. The States estimated annual savings between \$800,000 and \$7 million.

Twenty of the 30 States using the revised prices either did not believe or were unsure that the revised prices would result in long-term cost savings. Many of these States felt that

providers and manufacturers would find ways to circumvent the new prices. For instance, manufacturers could obtain new national drug codes for products with revised prices and report a higher average wholesale price for the new code. Because First DataBank only reported revised prices for the national drug codes that were supplied by the Justice Department and the NAMFCU, Medicaid would pay the higher prices reported for the newly-issued national drug codes. Furthermore, because the revised prices were issued on a product-specific and not a drug-class level, providers could substitute drugs with higher-priced national drug codes in place of codes with revised prices.

CONCLUSION

Over the last several years, the OIG has produced a significant body of work that clearly demonstrates the inflated nature of reported average wholesale prices. Because most States base their reimbursement for drugs on average wholesale prices, this inflation has caused Medicaid to pay too much for certain products. Therefore, we commend any efforts to obtain more accurate pricing for the Medicaid program.

This report shows that some States are benefitting from the revised average wholesale prices prompted by the actions of the Justice Department and the NAMFCU. However, States' concerns about the revised prices indicate that attempting to lower reimbursement simply by further reducing average wholesale prices may not be an effective long-term solution. Therefore, we continue to believe that the current system's reliance on reported average wholesale prices as a basis for drug reimbursement is fundamentally flawed.

Agency Comments

The CMS agreed with our conclusion that the reliance on reported average wholesale prices as a basis for drug reimbursement is problematic, and stated that they will continue to look for administrative and legislative solutions to this problem. In addition, the CMS made two technical comments concerning items in the draft report. We have addressed the technical comments in this final version of the report. The full text of CMS' comments is presented in Appendix B.

APPENDIX A**Use of Revised Average Wholesale Prices by State**

State	Uses Revised Prices for Pharmacy Drugs	Uses Revised Prices for Physician Drugs	
Alabama ¹	x	x	x
Alaska	x		
Arizona			
Arkansas			
California			
Colorado			
Connecticut	x		x
Delaware	x	x	
District of Columbia ²	x		x
Florida	x		
Georgia			
Hawaii ³	x	x	x
Idaho ⁴	x		x
Illinois	x		
Indiana ²	x	x	x
Iowa			
Kansas ⁴	x	x	
Kentucky ⁵			
Louisiana			
Maine			
Maryland	x		x
Massachusetts			
Michigan			
Minnesota ⁵			
Mississippi			
Missouri ⁵			
Montana	x		
Nebraska			
Nevada	x		x
New Hampshire	x		x
New Jersey	x		
New Mexico	x		x
New York	x		x

APPENDIX A

State	Uses Revised Prices for Pharmacy Drugs	Uses Revised Prices for Physician Drugs	Subtracts Discount from Revised Price
North Dakota ⁵			
Ohio ¹	x		x
Oklahoma	x		x
Oregon ⁴	x	x	x
Pennsylvania	x	x	x
Rhode Island			
South Dakota			
South Carolina	x	x	x
Tennessee ⁶	x		x
Texas ^{1, 4}	x		
Utah	x		
Vermont	x		x
Virginia			
Washington	x		
West Virginia	x		
Wisconsin ⁷	x	x	x
Wyoming			

Source: OIG Survey of Medicaid States, January - March 2001

¹ State does not use revised prices for many of the affected drugs because State relies on methods other than average wholesale price as its primary reimbursement methodology.

² State no longer uses revised prices for blood-factor products based on complaints from providers.

³ Revised prices not available to all State contractors.

⁴ For a small number of national drug codes, State no longer uses revised prices since invoices sent by providers indicated prices were too low.

⁵ State used revised prices at one time, but no longer does so.

⁶ Most drugs are paid through a managed care organization. Only drugs provided to dual-eligible Medicare/Medicaid recipients and behavioral-health drugs are reimbursed through the pharmacy program.

⁷ State does not use revised prices for drugs with State maximum allowable costs.

APPENDIX B

Health Care Financing Administration Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: AUG 20 2001

TO: Janet Rehnquist
Inspector General

FROM: Ruben J. King-Shaw, Jr.
Deputy Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicaid's Use of Revised Average Wholesale Prices* (OEI-03-01-00010)

Thank you for the opportunity to review and comment on the above-referenced draft report regarding state Medicaid agencies' use of revised average wholesale prices (AWPs) for certain prescription drugs. Investigative findings by the Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCUs) revealed that some drug manufacturers were reporting inflated average manufacturer prices for certain drug products. As a result, actual wholesale pricing data were collected for approximately 400 national drug code numbers representing 51 drugs. These data were provided to First Data Bank, which made the prices available to state Medicaid programs. The OIG reported that some states are benefiting from the revised (AWPs); however, states are still concerned that this may not be an effective long-term solution.

While there were no recommendations noted in this report, the Centers for Medicare & Medicaid Services agrees with OIG's conclusion that reliance on reported AWPs by drug manufacturers as a basis for drug reimbursement is problematic. Additionally, we acknowledge OIG's comments in earlier reports regarding the shortcomings of using AWPs as a basis for reimbursement and will continue to look for administrative and legislative solutions to this problem.

We appreciate the effort that went into this report and the opportunity to review and comment on the issues it raises. Finally, we note as a technical correction that there appears to be a discrepancy between page i, first paragraph, and page 1, first paragraph under "Medicaid Coverage of Prescription Drugs." The total amount of Medicaid payments for prescription drugs for 1998 differs in each section depending on whether the OIG is using the total amount of Medicaid payments before rebates, or net rebates. The \$14 billion on page i represents prescription payments with rebates. The \$12 billion on page 1 represents the prescription payments' net rebates.

APPENDIX B

Page 2 – Michael F. Mangano

The OIG concludes that because most states base their reimbursement for drugs on AWP, inflated AWP have “caused Medicaid to overpay for these products.” (See pages ii (Conclusion) and 9 (first paragraph.)) Since the regulations and relevant state plans authorize payment for drugs based on AWP, regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have “overpaid” for drugs. We therefore recommend that the sentences on pages ii (penultimate paragraph, second sentence) and 9 (first paragraph, second sentence) be deleted.